Supreme Court, U. S.
FILED
JUL 28 1980
MICHAEL RODAK, JR., CLERK

NO. 80-259

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 W. Randolph St.
Chicago, Ill. 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City,
Oklahoma 73102
(405) 235-8593

Attorneys for Petitioners

NO.

---

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

---

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

---

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

---

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 W. Randolph St.
Chicago, Ill. 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City,
Oklahoma 73102
(405) 235-8593

Attorneys for Petitioners

## QUESTIONS PRESENTED

1. Whether Laetrile is exempt from the premarketing clearance requirements of the Federal Food, Drug, and Cosmetic Act by operation of the Act's 1962 grandfather clause.

2. Does denying cancer patients the right to use a nontoxic substance in connection with their personal health infringe constitutionally protected privacy interests?

PARTIES

GLEN L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients,

Petitioners,

vs.

UNITED STATES OF AMERICA, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, et al.,

Respondents.

TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF AUTHORITIES | v |
| OPINIONS BELOW | 1 |
| JURISDICTION | 2 |
| CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED | 3 |
| STATEMENT OF CASE | 6 |
| REASONS FOR GRANTING WRIT | 10 |
| Introduction | 10 |
| Cancer, the Underlying Problem. | 12 |
| Laetrile Is Exempt from the Premarketing Clearance Requirements of the Federal Food, Drug, and Cosmetic Act by Operation of the Act's 1962 Grandfather Clause | 17 |
| Laetrile "Generally Recognized as Safe" | 23 |
| The FDA "Double Standard of Safety" | 24 |
| Denying Cancer Patients the Right to Use a Nontoxic Substance in Connection with their Personal Health Infringes Constitutionally Protected Privacy Interests | 28 |

Page

CONCLUSION..... 42

APPENDIX..... A-1

TABLE OF AUTHORITIES

Cases


| | Page |
|---|---|
| Application of President and Directors of Georgetown College, 331 F.2d 1010 (D.C. App. 1964) | 31 |
| Doe v. Bolton, 410 U.S.,1979 (1973) | 33,35 |
| Eisenstadt v. Baird, 465 U.S. 438 (1972) | 33 |
| Erickson v. Dilgard, 252 N.Y.S. 2d 705 (1962) | 32 |
| Griswold v. Connecticut, 381 U.S. 471 (1965) | 30,33 |
| In Matter of Quinlan, 355 A.2d 647, cert. den.,429 U.S. 922 (1976) | 39 |
| Jacobson v. Massachusetts, 197 U.S. 11 (1904) | 32, 37,40 |
| Kent v. Dulles, 357 U.S. 116(1958) | 36 |
| Olmstead v. United States, 277 U.S. 438 (1928) | 30 |
| Roe v. Wade, 410 U.S. 113 (1973) | 30,33, 34,38, 39 |
| Rutherford v. U. S., 542 F.2d 1137 (10th Cir. 1976) | 21,22 |
| Schloendorff v. Society of New York Hospital, 211 N.Y. 125 (105 N.E. 92) | 31 |

Whalen v. Roe, 429 U.S. 589,
51 L. Ed. 2d 64..... 37,38

Other Authorities

Merck Index (1907 Ed. 1940 Ed. and
Current - 9th Ed.)..... 18

Physicians' Desk Reference, 33rd
Ed., 1979..... 26

5 U.S.C.A., Sec. 554(c)..... 22
5 U.S.C.A., Sec. 556(d)..... 22

Section 201(p) of the Federal Food,
Drug, and Cosmetic Act..... 23

42 Fed. Reg. 10066 (1977)..... 19

42 Fed. Reg., No. 151, Page 39768..... 18

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1980

GLEN L. RUTHERFORD, et al.,

Petitioners,

vs.

UNITED STATES OF AMERICA, et al.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE TENTH CIRCUIT

To the Honorable, the Chief Justice and Associate Justice of the Supreme Court of the United States:

GLEN L. RUTHERFORD, et al., the petitioners herein, pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Tenth Circuit entered in the above-entitled case on February 19, 1980.

OPINIONS BELOW

After the United States Court of

Appeals for the Tenth Circuit remanded the case to the Food and Drug Administration (542 F. 2d 1137), the District Court, Honorable Luther L. Bohanon, District Judge presiding (at 438 F. Supp. 1287), ruled in favor of petitioners and the U. S. Court of Appeals for the Tenth Circuit (at 582 F. 2d 1234), affirmed in part.

On grant of certiorari, this Court (at 442 U. S. 544, 99 S. Ct. 2470, 61 L. Ed. 2d 68) reversed and remanded for the 10th Circuit U. S. Court of Appeals to rule upon the issues as determined by the District Court.

The opinion of the United States Court of Appeals for the Tenth Circuit, on remand, reversing and remanding the decision of the District Court, is reported at 616 F. 2d 455 and is included in the Appendix hereto, infra, page A-1.

## JURISDICTION

The judgment of the United States Court of Appeals for the Tenth Circuit (Appendix, infra, page A-1) was entered on February 19, 1980. A timely petition for rehearing was denied on April 28, 1980. (Appendix, infra, page A-12) The jurisdiction of the Supreme Court is invoked under 28 U. S. C. 1254(1).

## CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

1. Amendment I to the United States Constitution

2. Amendment IV to the United States Constitution

3. Amendment V to the United States Constitution

4. Amendment IX to the United States Constitution

5. Amendment XIV to the U. S. Constitution

6. 21 U.S.C.A., Section 321(g)(1):

> "The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

7. 21 U.S.C.A., Section 321(p), provides in pertinent part:

> "The term 'new drug' means --
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof."

8. Section 107(c) of the Drug Amendments

of 1962, Pub. L. No. 87-781 (76 Stat.789)

(1962 grandfather clause) provides:

> "In the case of any drug which, on the day immediately preceding the enactment date (October 10, 1962) (A) was commercially used or sold in the United States, (B) was not a new drug as defined by Section 201(P) of the Basic Act as then in force (21 U.S.C.A. 321(p)) and (C) was not covered by an effective (new drug) application under Section 505 of that (Act 21 U.S.C. 355), the amendments to Section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended or suggested in labeling with respect to such drug on that day."

9. 5 U.S.C.A., Section 706, Scope of Review:

> "To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall --
>
> (1) compel agency action unlawfully withheld or unreasonably delayed; and
>
> (2) hold unlawful and set aside agency action, findings, and conclusions found to be --
>
> (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
>
> (B) contrary to constitutional right,

power, privilege or immunity;

(C) In excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) Without observance of procedure required by law;

(E) Unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) Unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing Court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error."

STATEMENT OF CASE

By way of background, in 1975, terminally ill cancer patients and their spouses brought this action to enjoin the Government from interfering with the interstate shipment and sale of Laetrile, a drug widely used by cancer patients and their Doctors.

Finding that Laetrile, in proper dosage, was non-toxic and effective, the District Court ordered the Government to permit

limited purchases of the drug by one of the named plaintiffs. 399 F. Supp. 1205, 1215 (WD Okla. 1975). On appeal by the Government, the 10th Circuit U. S. Court of Appeals did not disturb the injunction. However, it instructed the District Court to remand the case to the Food and Drug Administration for determination whether Laetrile was a "new drug" under Sect. 201(p)(1),and if so, whether it was exempt from premarketing approval under either of the Act's grandfather clauses. 542 F.2d 1137 (1976).

After completion of administrative hearings, the Commissioner issued his opinion on July 29, 1977; 42 Fed. Reg. 39768 (1977), that Laetrile was a "new drug" requiring premarket approval, it not being exempted because "generally recognized as safe and effective", or exempted under the 1938 and 1962 "grandfather clauses" of the Federal Food, Drug and Cosmetic Act.

On review of the Commissioner's decision, the District Court, concluding that the record did not support the Commissioner's findings as to the 1962 grandfather provision, ruled that Laetrile was entitled to an exemption from premarketing approval requirements. 438 F. Supp. at 1294-1298. Alternatively, the Court held that, by denying cancer patients the rights to use a nontoxic substance in connection with their personal health, the Commissioner had infringed constitutionally protected privacy interests. Id., at 1298-1300.

Meanwhile, by order entered April 8, 1977, the District Court certified a class consisting of terminally ill cancer patients. 429 F. Supp. 506 (WD) Okla. 1977). The Government did not seek review of that order. The District Court had also entered orders for individuals who submitted affidavits averring their membership in the certified

class of cancer patients. This "affidavit system" is currently in effect, making possible availability of Laetrile to U. S. cancer patients and their physicians, whether or not they reside in one of the 22 states which have specifically enacted Laetrile enabling laws, or elsewhere.[1]

Following the District Court rulings, and further proceedings in the 10th Circuit U.S. Court of Appeals and this Court, the cause was remanded to the U. S. Court of Appeals for review of the District Court's rulings on the constitutional and grandfather clause questions. (United States v. Rutherford, 442 U.S. 544, at 559 note 18,

---

1. Alaska (See Alaska Statutes 08.64.367); Arizona (See A.R.A. 36-2451); Delaware (See Del. Code Ann. 16 Section 4901); Florida (See F.S.A. 458.24); Idaho (See Idaho Code 18-7301A); Illinois (See S.H.A. 56½, Section 1801); Indiana (See Burns Ind. St. Ann. 16-8-8-1); Kansas (See S.B. 505 May 8,1978); Louisiana (See L.S.A. -- R.S. 40:676); Maryland (See Ann. Code of MD, Art 43 Sec.

(June 18, 1979).

On February 19, 1980, the Court of Appeals reversed the District Court, ruling against petitioners on the Constitutional and Grandfather clause questions.

Petitioners timely filed their petition for rehearing, which was denied on April 28, 1980.

## REASONS FOR GRANTING WRIT

### Introduction

This cause involves fundamental Constitutional issues of transcendant importance that affect an entire class of persons, namely terminally ill and other cancer

---

1 (continued)

133 ch 809); Nevada (See Nev. Rev. St. 630.303); New Hampshire (See R.S.A. 329;30); New Jersey (See N.J.S.A. 24:6F-1); North Dakota (See H.B. 1214 eff. July 1, 1979); Oklahoma (See 63 Okl. St. Ann. Sec. 2-313); Oregon (See Oregon Rev. St. 689.885); South Dakota (Bill Number 1287 signed 3/16/79 eff. 7/1/79); Texas (See Vernon's Ann. Civ. St. 71 art.4476-5a); Washington (See R.C.W.A. 70.54.130); Montana and Colorado have also enacted Laetrile legislation, and, in 1980,

patients, the number of cancer patients currently receiving Laetrile, or Amygdalin, pursuant to the legalities heretofore rendered in this cause, comprising 75,000 or more persons. If the FDA is successful herein, as it has been thus far, no one, not even a terminal cancer patient, may receive Laetrile in any form, and thousands of patients now dependent upon Laetrile will be effectively left to die without the treatment they now value for their very lives.

Petitioners respectfully submit that grave and important issues of Due Process and Constitutional Rights to Privacy are present in the above cause, and that it is

---

1 continued

Kentucky. Certain state laws, such as enacted in Illinois, include provisions for "informed consent" to be rendered by the treating physician, and acknowledged by the cancer patient, before treatment with Laetrile commences. In the main these statutes properly equate "Laetrile" and "Amygdalin". All of these State laws were enacted only after

appropriate that this Court consider, on writ of certiorari, all of the issues involved.

Petitioners therefore pray that this Court's discretion be exercised in this case and that a writ of certiorari issue to review the judgment of the United State Court of Appeals for the Tenth Circuit (appendix, infra, page A-1), if only because said Court of Appeals has decided important questions of Constitutional and Federal law which have not been, but should be, settled by this Court.

Cancer -- The Underlying Problem

In 1977, 400,000 Americans died of cancer, a figure which is seven times the total fatalities in the Vietman and Korean Wars.

1 continued

extensive hearings, research, and debate. Laetrile legislation is presently pending in various other States. Rather obviously, banning Laetrile for interstate shipment to a cancer patient would nullify all of the

According to Dr. Marvin Schneiderman, Associate Director of the National Cancer Institute, a government agency which receives approximately $800,000,000.00 per year in taxpayers' funds, the death rate from all types of cancer is continuing to increase. Dr. Schneiderman also states that cancer mortality, overall, is increasing, so that it is the only major cause of death which has continued to rise from 1900 through 1976. Putting it another way, more people are dying from cancer in every age group than have died from cancer in such age groups at any other time in American history. According to present projections, 1 in 4 Americans is doomed to die of cancer. Pursuant to the best available Government

---

1 continued

existing State Laetrile laws, and State sanction of Laetrile use where such legislation has not yet been enacted.

statistics, the cancer death rate in 1900 was 64 per 100,000 of the population, a figure which has now increased to 162.8 per 100,000, or almost a three-fold increase. As recently as 1965, the cancer death rate per 100,000 persons was only 127.9. Within the overall statistics, there are equally unfavorable figures as to specific types of cancer. For example, between 1973 and 1975, the number of lung cancer cases increased in the United States 13%, breast cancer, 17%, stomach cancer, 28%, and prostate cancer, 32%, for the same period. Nor is median survival time particularly encouraging for the cancer sufferer. According to the U. S. Department of Health, Education, and Welfare, the observed median survival time in approximately 219,500 cases of cancer (all sites) was 1.7 years. This median survival time includes those cases wherein a cancer is localized, or limited to the site or origin. Of great interest to the

matter at bar, however, are the statistics concerning distant (disseminated or "metastasized") cancer, wherein the U. S. Government has stated that the five-year relative survival rate ranges from a maximum of 17% for prostate cancer, to 14% for corpus uteria cancer, 12% for cervix cancer, 10% for female breast cancer, 8% for ovary cancer, 5% for colon cancer, 2% for stomach cancer, 1% for lung and bronchur cancer, and a "zero" survival rate for pancreas cancer for that period. The overall death rate for those afflicted by distant or disseminate cancers, after a period of five years, is 91%.[2]

Petitioners consider this latter figure to be of particular significance herein, due to

---

2. See testimony of Dr. Marvin Schneiderman, Associate Director, National Cancer Institute, March 5, 1979, before Special Subcommittee, U. S. Senate, Edward Kennedy, Chairman;"Facts of Life and Death", U. S. Department of Health, Education, and Welfare Publication No. (HRA) 74-1222; "Mortality Trends for Leading Causes of Death", U. S. Department of Health,

the fact that the plaintiffs, together with thousands of other patients who have availed themselves of Laetrile or amygdalin are "terminal", namely, no conventional therapy is of any avail to prolong their lives beyond the dismal life span heretofore shown by the government's statistics, and which inescapably reflect the inadequacy and inefficacy of conventional cancer therapies. Thus, Petitioner Rutherford and those others who have petitioned the Courts, and who also have been recognized by the legislatures of 22 states to date, believe that Laetrile offers hope as against virtually no hope whatsoever from conventional therapies.

Basic to the arguments heretofore presented to this Court by FDA is the "rosy", but totally

---

2 Continued

Education, and Welfare Publication No. (HRA) 74-1853; "Ca-Cancer Journal for Clinicians"; "Cancer Rates and Risks", 2nd Edition, U. S. Department of Health, Education, and Welfare Publication No. NIH 75-691.

unjustified "imputation" that with orthodox, or conventional, cancer therapies we are rapidly winning the battle against cancer,and that, therefore, we need look no further to such therapies as those afforded by Laetrile, and its accompanying metabolic therapies as employed by physicians throughout the United States, and over the World. However, as noted hereinbefore, the Government's own statements and statistics demonstrate that we are not winning the battle against cancer, but losing it very rapidly, the conventional therapies being totally inadequate to handle the problem.

Laetrile Is Exempt from the Premarketing Clearance Requirements of the Federal Food, Drug, and Cosmetic Act by Operation of the Act's 1962 Grandfather Clause

This Court's previous decision did not rule upon this issue, merely remanding this cause to the U. S. Court of Appeals for such ruling.

The District Court found that in every respect, Laetrile met the criteria of the "1962 Grandfather Clause" to the Federal Food,

Drug, and Cosmetic Act, its opinion detailing at length the underlying and substantiating reasons therefor.

Certiorari should be granted herein if only because the Appeals Court's recent opinion herein misconstrues the factual circumstances and also the factors involved as to the "grandfathering" of Laetrile, or amygdalin, pursuant to the 1962 statute in question. For example, the Appeals Court's opinion stated "there has not been the consistency in the formula which the FDA requires under its current practice."

This is entirely contrary to fact, even as noted in the"Commissioner's Decision on Status" (42 Federal Register, No. 151, Page 39768, et seq.), wherein the FDA Commissioner noted that the Merck Index, 9th Edition, designates "laetrile" as "a term used interchangeably with 'Laetrile', 'amygdalin', nitriloside', and 'vitamin B-17'." The record also clearly shows that the chemical composition of

"amygdalin", or "Laetrile", is now new, but has been known to science since at least 1845.

The Commissioner himself recognized the simple identity of the substance which was the subject of his rule-making proceeding when the first notice of rule making was published, 42 Fed. Reg. 10066 (1977):

> "Laetrile is the name of a product whose major component or ingredient is Amygdalin, a substance that occurs naturally in the pits of apricots, peaches, bitter almonds and in other plant material ... and its has been known, tested and used (as a cancer remedy) for more than twenty-five years ..."

Similar references to the factual circumstances which support all of the criteria necessary to constitute Laetrile, or amygdalin, as being "grandfathered" can be cited. These are covered in great detail by the District Court's rulings below. (See 435 F. Supp. 1287).

In this regard, however, perhaps the most serious and substantial misconstrual of the matters relating to whether or not Laetrile is

"grandfathered" relate to the AppealsCourt's rulings concerning the administrative record before the U. S. Food and Drug Administration. In effect, the Court's recent opinion reverses the "burden of proof" which was incumbent upon FDA, placing it upon petitioners, and also, in substance, attributing the blame for alleged inadequacies in the administrative record upon petitioners, as well.

FDA opposition to Laetrile has been implacable, even as the within cause was commenced in 1975, when petitioner Rutherford's Laetrile having been seized by FDA, he sought Court intervention. At that time, FDA had conducted no administrative proceedings whatsoever to determine the legal status of Laetrile. On October 12, 1976, the Appeals Court upheld the District Court, its opinion stating that Laetrile "is not a new drug merely because they" (i.e., FDA) "say it is." The Court then ordered an administrative review by FDA, which in turn led to the rulemaking proceeding mentioned in the Appeals Court's most recent opinion.

By the order of the Appeals Court upon its remand of this case to the Food and Drug Administration, (Rutherford v. United States, 542 F. 2d 1137 (10th Cir. 1976) ), it was stated:

> "To support its determination, the FDA in the case at bar would have to present substantial evidence to support the proposition that Laetrile is not generally recognized among qualified experts as 'safe and effective' and that Laetrile is not grandfathered by either of the exemptions discussed above."

The administrative proceeding belied any openminded review by the Food and Drug Administration. In the matter at hand, the FDA Commissioner elected to conduct hearings under provisions for the most informal proceedings allowed. These informal proceedings inevitably resulted in a denial of the right to cross-examine witnesses, also allowing testimony to be given without requiring an oath. Petitioners' attorneys objected to this procedure, but the Hearing Examiner proceeded nevertheless (Administrative Rule Making Hearing, Oral Argument, pp. 10, 11, 27 and 28).

Contrarily, the Appeals Court had mandated hearings which would guarantee cross-examination, pursuant to 5 U.S.C.A., Section 554(c). Rutherford v. U.S., 542 F. 2d 1137 (1976). The cited provision comprehends that hearings conducted thereunder must be pursuant to Sections 556 and 557 of the Administrative Procedure Act. Section 556 of the Act provides under sub-part (d):

> "... a party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence and to conduct such cross-examination as may be required for a full and true disclosure of the facts..."

However, FDA deliberately denied petitioners their proper administrative proceedings mandated by the Appeals Court, and generally carried out the proceedings in such a way as to guarantee that the FDA's already predetermined position on Laetrile would prevail.

Any "frailties", therefore, in the administrative record before FDA were, and are, the sole and only responsibility of the Agency itself, and should not have been cause to reverse

the findings of the District Court that indeed Laetrile is "grandfathered" pursuant to the appropriate provisions of the Federal Food, Drug, and Cosmetic Act. The record herein, nevertheless, amply reveals that FDA did not meet its burden of proof as mandated by the Court, nor did it conduct proper administrative proceedings, as also mandated by the Appeals Court.

Even then, to the maximum extent possible, and acting under the handicaps aforesaid, the record herein does reveal that all of the criteria of the 1962 Grandfather Clause were met. This Court should therefore grant certiorari, with the above in view.

Laetrile"Generally Recognized as Safe"

There is no question but that a drug meeting the criteria of the 1962 Grandfather Clause, as indeed Laetrile does, is an exempted substance if it also was, as of October 9, 1962, "generally recognized, among experts qualified to evaluate the safety of drugs, as safe for use..." (Section 201(p) of the Act as in effect

October 9, 1962).

The District Court, based upon ample support in the record, found that Laetrile "was generally recognized as safe" and otherwise met the criteria of the 1962 Grandfather Clause.

The Court's findings included:

> "Extensive use of the substance, its commercial availability, and its recognition as being safe, all previous to 1962, are well documented in the record."

And:

> "The administrative record brooks little real controversy as to Laetrile's non-toxicity, particularly when administered parenterally, even at doses greatly exceeding amounts normally ingested."

The District Court's findings regarding the "safety" and "generally recognized as safe" 1962 status of Laetrile were not rendered in a "vacuum", so to speak, but with ample substantiation in the record.

The FDA "Double Standard" of Safety

In an attempt to reverse these findings, respondents herein represented to this Court in previous proceedings that somehow Laetrile is "not safe", but "toxic" (in the oral form, at least), and that therefore Laetrile does not

meet the alleged "strict standards" of "safety" which are purportedly a prerequisite to Food and Drug Administration approval of any anti-cancer drugs.

Nevertheless, nowhere in the voluminous proceedings of this cause, has FDA indicated what such "safety" standards might be, to be applied by this Court.

Whatever the case, presumably FDA has applied standards of "safety" in numerous instances whereby anticancer drugs have been approved by the Agency for use by physicians, and for administration to cancer patients.

However, in fact very toxic, grossly dangerous, lethal and fatal "anticancer" drugs have been approved in the name of "safety" by the Agency, while FDA has not even-handedly and non-discriminatorily applied to Laetrile the same standards by which it measures other anticancer drugs for "safety".

Not one "anticancer" drug thus far approved by FDA for "safety" and "efficacy" is actually "safe", but such drugs are extremely toxic and

dangerous, even causing death, not to mention destroying the body's immune systems and actually causing cancer, among other things.[3]

---

3. Some of the "anticancer" drugs currently marketed with FDA approval include (information based upon FDA-approved labeling, and prepared by manufacturer, each instance, published in Physicians' Desk Reference, 33rd Edition, 1979): CYTOXAN (Mead Johnson & Co.), a drug which can cause death, and can also cause cancer; ADRIAMYCIN (Adria Laboratories, Inc), "Cardiac toxicity" is exhibited by this drug, and congestive heart failure and/or cardiomyopathy may be encountered. There is a "high incidence of bone marrow depression" and administration of the drug "may result in superinfection or hemorrhage"; ADRUCIL (Adria Laboratories, Inc.) A "highly toxic drug with a narrow margin of safety" and "severe hematologic toxicity, gastrointestinal hemorrhage, and even death may result" from use of the drug; BICNU (Bristol Laboratories, Division of Bristol Myers Co.) "Delayed bone marrow toxicity is the major toxicity", and the drug can cause cancer; DTIC (Dome Division, Miles Laboratories, Inc.) "Leukopenia and thrombocytopenia may be severe enough to cause death." ; MUTAMYCIN (Bristol Laboratories, Division of Bristol Myers Co.) "Bone marrow suppression, notably thrombocytopenia and leukopenia, which may contribute to overwhelming infections in an already compromised patient, is the most common and severe of the toxic effects of Mutamycin." The drug can also cause cancer, with an increase of 50% to 100% in cancer tumors; MATULANE (Roche Laboratories) It can be cancer-causing

How, in the face of the "anticancer" drugs approved by FDA for their "safety" could anyone claim that Laetrile is not only totally "safe, but "generally recognized as safe", as well, either now or in 1962? Petitioners respectfully urge that a rule of common sense should be applied to the criteria as to Laetrile, and concerning which the same is

---

3. Continued

"Leukemia, among other things, has resulted from Matulane therapy"; MITHRACIN (Manufactured by Pfizer Laboratories for the Dome Division, Miles Laboratories, Inc.) "Severe thrombocytopenia, a hemorrhagic tendency and even death may result from the use of Mithracin."; FUDR (Hoffman LaRoche, Inc.) "Severe hemotological toxicity, gastro-intestinal hemorrhage and even death may result from the use of FUDR despite meticulous selection of patients and careful adjustment of dosage ..."; FLUORACIL (Hoffman LaRoche, Inc.) "Severe hemotological toxicity, gastrointestinal hemorrhage and even death may result from the use of Fluorouracil despite meticulous selection of patients and careful adjustment of dosage."; METHOTREXATE (Lederle Laboratories) "Sudden death has been reported from use of Methotrexate."; BLENOXANE (Bristol Laboratories, Division of Bristol Myers Co.) "Pulmonary fibrosis" (i.e.,progressive fibrous degeneration of the lung" is the most severe toxicity associated with Blenoxane."

totally "nontoxic", and "safe", if only judged by the standards heretofore applied by FDA itself as to approved drugs now available and employed by Doctors for their cancer patients.[4]

## Denying Cancer Patients the Right to Use a Nontoxic Substance in Connection with their Personal Health Infringes Constitutionally Protected Privacy Interests

Contrary to the detailed and exhaustive findings and opinion of the District Court, the Appeals Court's recent opinion finds that petitioners have no constitutional right of privacy as to use of Laetrile. In so finding, it is respectfully submitted that such Court applied the wrong standard in evaluating whether or not petitioners do indeed have a constitutional right of privacy in this area.

4. Petitioners note a recent report (United Press International, June 28, 1980) that Laetrile, administered to human cancer patients at the Mayo Clinic, under National Cancer Institute auspices, has passed safety tests.

In particular, the Appeals Court's recent opinion disclaims any "useful purpose" to review a number of this Court's decisions regarding constitutional rights of privacy in various health areas, concluding that petitioners herein would have no right of privacy as to Laetrile inasmuch as the denial thereof is "within the area of governmental interest".

However, the Constitutional standard to be properly applied in this regard is not as stated by the lower Court, but whether or not there is a"compelling governmental interest" to deny Laetrile to terminal and other cancer patients. In this regard, petitioners cite the numerous citations of this Court, hereinafter mentioned in part.

It is also submitted that the lower Court's recent opinion fails to take into account an equally important "area of governmental interest" inherent in the fact that twenty-two States have thus far enacted legislation specifically permitting and approving the use

of Laetrile for their citizens, and wherein there is actually recognition, therefore, of a "compelling governmental interest" in making available Laetrile to cancer patients in those states.

The Right of Privacy was first enunciated by this Court in Griswold v. Connecticut, 381 U.S. 471 (1965). The right has been found to emanate from the penumbras of the 1st, 4th, 5th, 9th and 14th Amendments to the Constitution. Roe v. Wade, 410 U. S. 113 (1973). The Privacy Right has been recognized as "fundamental". Griswold v. Connecticut, supra.

The language of Mr. Justice Brandeis in his dissenting opinion in Olmstead v. United States, 277 U. S. 438, 478 (1928), remains vital today:

> "The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans and their beliefs, their

their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone -- the most comprehensive of rights and the right most valued by civilized men. To protect that right, every unjustifiable intrusion by the government upon the privacy of the individual, whatever the means employed, must be deemed a violation..."

Judge Cardozo (and later Justice of this Court) in Schloendorff v. Society of New York Hospital, 211 N.Y. 125 (105 N.E. 92, page 93) stated:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body;..."

The right to control one's own body is not restricted to the wise; it includes the "foolish"refusal of medical treatment. Nor is this right limited in its recognition to any single segment of the political, economic, or social thought spectrum.

In Application of President and Directors of Georgetown College, 331 F. 2d 1010, 1017 (D.C. App. 1964), Judge (now Chief Justice of this Court) Burger, in his now well-known dissent, commented upon the applicability of

Mr. Justice Brandeis' concept of the Right of Privacy:

> "Nothing in this utterance suggests that Justice Brandeis thought an individual possessed these rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest that he intended to include a great many foolish, unreasonable, and even absurd ideas which do not conform, such as refusing medical treatment, even at great risk."

The right to refuse any and all medical treatment has been recognized by the Supreme Court. Jacobsen v. Massachusetts, 197 U.S. 11 (1904). This same principle has been affirmed even despite risk of death. Erickson v. Dilgard, 252 N.Y.S. 2d 705, 706 (1962). The Court in Erickson stated:

> "... it is the individual who is the subject of a medical decision who has the final say and that this must necessarily be so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."

To recognize a right to decline medical attention of any kind, while denying a right of terminal cancer patients to utilize the

nontoxic substance Laetrile, would create a bizarre anomaly in the law.

The District Court's decision herein, allowing the use of Laetrile by terminally ill cancer patients, falls within the Right to Privacy previously enunciated by this Court.

This Court has dealt with the privacy right in several recent cases within a health context. Roe v. Wade, supra; Doe v. Bolton, 410 U.S. 179 (1973); Griswold v. Connecticut, supra; and Eisenstadt v. Baird, 465 U. S. 438 (1972).

In Griswold, it was held that a state could not ban the use of contraceptives without abridging a couple's right to privacy which underlies a marriage relationship. The Court recognized the Right of Privacy within the general spirit of health care.

Eisenstadt upheld the right of a person to distribute contraceptives on grounds that statutes prohibiting distribution to single people violated equal protection by distinguishing between the married and single people.

The Court stated at 453:

> "If the Right of Privacy means anything, it is the right of the individual, married or single, to be free from unwarranted government intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."

In the landmark case, Roe v. Wade, supra, this Court expanded the Right of Privacy to encompass a woman's decision to have an abortion. The Court found that the right to an abortion was a "fundamental" right.

The decision in Roe, supra, was based, at least in part, on the health of the mother. Roe at 727:

> "The detriment that the State would impose upon the pregnant woman by denying this choice altogether is apparent. Specific and direct harm, medically diagnoseable even in early pregnancy may be involved. Maternity, or additional offspring, may force upon a woman a distressful life in the future. Psychological harm may be eminent. Mental and physical health may be taxed by child care."

Certainly the psychological and physical well-being of the terminally ill cancer patients herein deserves as much protection by this Court as the "possible" harm to a woman

as a result of child care, caused by the lack of an abortion. Regardless of the weight given the health factor in Roe, the health of the pregnant woman is inextricably involved in the Court's rationale allowing abortions.

In declaring the statutes prohibiting abortion to be unconstitutional, the Court balanced that right against what was asserted by many as the "Right to Life" for the unborn fetus.

Even considering the asserted rights of the unborn fetus, this Court did not find them strong enough to deny the mother's right to privacy.

Doe v. Bolton, supra, another abortion case handed down by this Court on the same day as Roe, also struck down criminal abortion statutes as unconstitutional.

Mr. Justice Douglas, in his concurring opinion in Doe v. Bolton, 410 U.S. 179, 213 (1973), recognized the fundamental nature of the freedom to care for one's own health:

"Third is the freedom to care for one's health and person, freedom from bodily restraint or compulsion, freedom to walk, stroll,or loaf."

Mr. Justice Douglas commented further about the right to health care at page 219:

"The right to seek advice on one's health and the right to place reliance on the physician of one's choice are basic Fourteenth Amendment values. We deal with fundamental rights and liberties, which, as already noted, can be contained or controlled only by discretely drawn legislation that preserves the 'liberty" and regulates only phases of the problem of compelling legislative concern."

The privacy right includes the privilege of an individual to plan his own affairs, for "outside areas of plainly harmful conduct, every American is left to shape his own life as he thinks best, do what he pleases, go where he pleases." Kent v. Dulles. 357 U.S. 116.126 (1958).

Many of the cancer patients involved in this matter have heard the death sentence from their own doctors. They have been told that orthodox medicine holds no hope for them and that they are suffering from cancer in its

"terminal" state. They are perfectly free to decline treatment of any kind. Jacobson, supra. Yet, under the construction of the Food, Drug, and Cosmetic Act asserted by FDA, they may not seek hope from the nontoxic substance Laetrile.

Those patients with requisite wealth can avoid this bureaucratic ban by obtaining treatment in countries such as Mexico, where Laetrile is legal, even welcomed, but this alternative is not available to the poor or the bedridden.

The ban of Laetrile by the Food and Drug Administration has resulted in a severe limitation on cancer patients' exercise of free judgment in matters directly affecting the quality of their lives. It cannot be asserted that these terminal cancer patients are being granted their "right to be let alone" as long as they are denied free access to Laetrile.

In Whalen v. Roe, 429 U. S. 589, this Court considered the New York statutory requirements with respect to prescriptions for "dangerous,

legitimate" drugs. The requirement in question was that of notification. The Court balanced the invasion of the zone of privacy against the public's right involved and concluded that with respect to the particular type of drugs involved the statutes were a reasonable exercise of the state's broad police power. In so holding, the Court discussed the right of an individual to choice of treatment, saying:

> "Nor can it be said that any individual has been deprived of the right to decide independently, with the advice of his physician, to acquire and to use needed medication ... Within dosage limits which appellees do not challenge, the decision to prescribe, or to use, is left entirely to the physician and the patient." Whalen v. Roe, supra, 429 U.S. 589, 603 (51 L.Ed. 2d 64, 75-76, 97 S.Ct. 869, 878).

In the matter at hand, FDA would leave no such decision to either physician or patient.

Personal rights that may be deemed "fundamental" or "implicit" in the concept of ordered "liberty" are included in this guarantee of personal privacy (410 U.S. 113, 152, 35 L. Ed. 2d 147, 176). In his concurring opinion in the Roe case, Justice Douglas recognized that

the "freedom to care for one's health and person" comes within the purview of the right to privacy (410 U.S. 179, 213, 35 L.Ed. 2d 147, 188). Justice Douglas continued:

> "It is one thing for a patient to agree that her physician may consult with another physician about her case. It is quite a different matter for the State compulsorily to impose on that physician-patient relationship another layer or, as in this case, still a third layer of physicians. The right of privacy -- the right to care for one's health and person and to seek out a physician of one's own choice protected by the Fourteenth Amendment -- becomes only a matter of theory, not a reality when a multiple-physician-approval system is mandated by the State.
>
> * * *
>
> "The good-faith decision of the patient's chosen physician is overridden and the final decision passed on to others in whose selection the patient has no part. This is a total destruction of the right of privacy between physician and patient and the intimacy of relation which that entails." (Roe v. Wade, 410 U.S. 113, 219, 35 L.Ed. 2d 191,192).

In Matter of Quinlan, (355 A. 2d 647,cert. den., 429 U.S. 922, 1976), the Supreme Court of the State of New Jersey held in a declaratory judgment proceeding that the parent and guardian of an incompetent woman could assert

on her behalf her constitutional right to privacy. The Court further held that its decision need not be controlled by the consensus of opinion of physcians who were qualified experts, namely, that withdrawal of the support of a respirator would not conform to standard medical practices and would result in Karen Quinlan's death soon thereafter (355 A. 2d 647, 669). The decision on whether or not to remove the respirator properly rested with Karen's parents and attending physicians.

FDA has made no real argument that the use of Laetrile by terminal or other cancer patients would in any way, offend the rationale of Jacobson, supra, because there is no intrusion upon the "safety of the general public."

It is paradoxical that FDA appears more interested in a potential harm to their ostensibly rigid and inflexible "system" of control over drugs than in the human and other issues presented in this case.

Any "compelling state interest" protecting

its"system" asserted herein by FDA simply does not exist. Plaintiffs' constitutional rights of due process and privacy require that they and their doctors be granted access to Laetrile.

The issue is best framed in the language of the District Court (438 F. Supp. 1287) wherein Judge Bohanon noted:

> "As a nation, however, historically and continuously, we are irrevocably committed to the principle that the individual must be given maximum latitude in determining his own personal destiny.
>
> "To be insensitive to the very fundamental nature of the civil liberties at issue in this case, and the fact that making the choice, regardless of its correctness, is the sole prerogative of the person whose body is being ravaged, is to display slight understanding the essence of our free society and its constitutional underpinnings. This is notably true where, as here, there are no simple answers or obvious solutions, uncertainty is pervasive, and even the best efforts leave so much to be desired.
>
> "The final consequences are ultimately borne by those whose bodies are the battleground on which cancer's war is waged. Many perceive the drugs acquisition as a life and death matter, and are understandably frustrated and enraged over attempts by their government to deny them the right to decide for themselves questions of such a personal and grave nature."

The compelling nature of the health interest invoked by the plaintiff class of cancer patients falls within the spirit and intent of the privacy cases decided by this Court and the same protection should be granted them.

It should be noted that this Court's previous decision herein did not consider petitioners' rights of privacy.

## CONCLUSION

Any legal right plaintiffs possess to use Laetrile may be of academic value if secured only at some undetermined future time. For the cancer victim, the phrase "justice delayed is justice denied" contains special significance. Petitioners ask simply that this Court remember that the acquisition of Laetrile for their own consumption is, for them, a matter of life and death and not one rightly governed by legal niceties. Petitioners further ask that this Court reflect on the indescribable nature of the injury they must nevertheless attempt to describe, if they are to prevail here.

This injury is clearly more than minimal or trivial; it is unconstitutional.

For the foregoing reasons, Petitioners pray that their Petition for a Writ of Certiorari be granted, and that the judgment of the United States Court of Appeals for the Tenth Circuit be reversed.

Respectfully submitted,

KIRKPATRICK W. DILLING
DENNIS M. GRONEK
ROBERT E. ARMSTRONG
188 West Randolph Street
Chicago, Illinois 60601
(312) 236-8417

KENNETH RAY COE
101 Park Avenue
Oklahoma City, Oklahoma 73102
(405) 235-8593

GLEN L. RUTHERFORD, Individually and on behalf of a class composed of terminally ill cancer patients,

Plaintiffs-Appellees,

v.

UNITED STATES OF AMERICA, Joseph A. Califano, Secretary of Health, Education and Welfare, Donald Kennedy, Commissioner of the Food and Drug Administration, et al.,

Defendants-Appellants.

No. 77-2049

United States Court of Appeals,

Tenth Circuit.

Feb. 19, 1980.

Rehearing Denied April 28, 1980.

Terminally ill cancer patients brought suit to enjoin the United States from interfering with interstate shipment of sale of laetrile on ground that it had not been approved for distribution under the Federal Food, Drug, and Cosmetic Act. After remand was ordered to the Food and Drug Administration, 582 F.2d 1234, the District Court, Luther L. Bohanon, J., 438 F. Supp. 1287, ruled in favor of plaintiffs and the Court of Appeals, 542 F.2d 1137, affirmed. On grant of certiorari,

the United States Supreme Court, 442 U.S. 544, 99 S.Ct. 2470, 61 L.Ed.2d 68, reversed and remanded. After remand, the Court of Appeals, Seth, Chief Judge, held that: (1) proponents of laetrile did not conduct the research and laboratory testing required under prevailing agency procedures and by the Act and therefore they did not meet their burden to fulfill premarketing requirements, and (2) with folk medicine aspect of use of laetrile, requirements of grandfather clause of the Act could not be met by proponents of laetrile so as to permit application of grandfather exception.

District court reversed, case remanded.

See also 424 F.Supp. 105; 429 F. Supp. 506.

Drugs and Narcotics

Although decision by a patient whether to have a treatment or not is a protected right, his selection of a particular treatment, or at least medication, is within area of governmental interest in protecting public health.

Drugs and Narcotics

Proponents of laetrile did not conduct the research and laboratory testing required under prevailing agency procedures and by Federal Food, Drug and Cosmetic Act, thus, they did not meet their burden to fulfill pre-marketing requirements. Federal Food, Drug and Cosmetic Act, Section 505, as amended 21 U.S.C.A., Section 355.

Drugs and Narcotics

With folk medicine aspect of use of laetrile, requirements of grandfather clause of Federal Food, Drug and Cosmetic Act could not be met by proponents of laetrile so as to permit application of grandfather exception. Federal Food, Drug and Cosmetic Act, Section 201(p)(1) as amended 21 U.S.C.A., Section 321(p)(1).

---

Barry Grossman,Atty.,Dept. of Justice, Washington,D.C.(John H. Shenefield,Asst.Atty. Genl.,Catherine G.O'Sullivan,Peter L.DeLaCruz, Atty.,Dept.of Justice,Washington,D.C.,Richard M.Cooper,Chief Counsel,Eugene M.Pfeifer,Associate Chief Counsel for Enforcement,Food and Drug Division,Dept. of Health,Education,and Welfare,Rockville,Md.,of counsel and Arnold I. Friede Asst.Chief Counsel for Enforcement,

Food and Drug Division, Dept. of Health,Education, and Welfare, Washington,D.C.,with him on brief), for defendants-appellants.

Kenneth Ray Coe of Hunt,Thomas,Dawson & Gile, Oklahoma City,Okl.(Kirkpatrick W.Dilling of Dilling,Dilling & Gronek,Chicago,Ill., Dennis M.Gronek and Robert E.Armstrong,Chicago, Ill.,of counsel,with him on brief on remand), for plaintiffs-appellees.

Charles F. Wheatley,Jr., William T. Miller and Robert A. O'Neil of Wheatley & Miller, Washington, D.C., and Grace Powers Monaco of Fairman, Frisk & Monaco, Washington, D.C., on brief, for amicus American Cancer Society, Inc.

Before SETH, Chief Judge, BARRETT and McKAY, Circuit Judges.

SETH, Chief Judge.

The case was remanded by the Supreme Court by United States v. Rutherford, 544 U.S.442, 99 S.Ct.2470,61 L.Ed.2d 68, with a reversal of our Rutherford v. United States, 582 F.2d 1234 (10th Circ.).

We had held that there was no measure or standard to permit the application of the "effective" requirement in the statute as to Laetrile as a cancer treatment by injection with a doctor's recommendation for the terminally ill patient.

The Supreme Court in its opinion held that the "effectiveness" provision of the Act did apply regardless of whether the patient was terminally ill or not. The Court also refers to those persons who have in the past (since 1907) advanced "simple and painless cures for cancer, including, lineaments of turpentine, mustard, oil, eggs, and ammonia; peatmoss; arrangements of colored floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and 'Fountain of Youth' mixtures of spices, oil, and suet." The "effectiveness" of Laetrile as a <u>treatment</u> is to be demonstrated, and to be applied to those for whom no cure is presently available.

Thus, there can be no exceptions for the terminally ill; the "effectiveness" standard is so established, and we so recognize. The issues on remand are thus the application of the grandfather clauses in the two statutes, and the constitutional right of privacy. On remand, we considered the issues on the basis of the original oral arguments and briefs, and

on the briefs filed after remand.

We held in Rutherford v. United States, 542 F.2d 1137 (10th Circ.), that the FDA had the power to declare a substance a "new drug", citing Weinberger v. Hynson,Westcott & Dunning, 412 U.S.609,93 S.Ct.,2469,37 L.Ed.2d 207. We also there noted that in Weinberger the Court stated that such an order was reviewable. In Rutherford, we also stated:

> "However,the FDA has made an administrative determination that Laetrile is a new drug and this places the plaintiff in a position in which he has to admit that it is a new drug in order to get the FDA to move. As result he could not be heard to say that they have not effectively stymied the use of this drug. The FDA has done this without citing any facts whatsoever, merely a conclusion, ..."

Under these circumstances we also held:

> "We are unable, however to see how the FDA can escape the obligation of producing an administrative record to support its determination of the first and more fundamental issue that Laetrile is a new drug, for it is not a new drug merely because they say it is. Moreover, such a conclusory ruling precludes effective review under 5 U.S.C. Section 706(2)."

Also: "It seems obvious that there cannot be a court review unless there is a decent record made." The case was thus remanded to the

trial court on the new drug issue for further proceedings. Hearings by the FDA were thereafter directed by the trial court.

The FDA thereafter held what it refers to as rule-making hearings and received mostly unsworn statments although some affidavits were received. This "record" of several thousands of pages of such statements then went to the trial court and we ultimately reviewed it for Rutherford v. United States, 582 F.2d. 1234 (10th Cir.), and made some charitable remarks about it in the opinion. It must,however, be stated that our review of such a record does not necessarily mean that a similar record will again be reviewed by this court.

But as to the remaining issues, the trial court held that the petitioners had a right "to be let alone," or a constitutional right of privacy to permit them, as terminally ill cancer patients, to take whatever treatment they wished regardless of whether the FDA regarded the medication as "effective" or "safe."

(1) It would serve no useful purpose to

review the series of Supreme Court opinions treating the privacy issue. These include Whalen v. Roe, 429 U.S.589,97 S.Ct.869,51 L. Ed.64; Planned Parenthood of Missouri v. Danforth, 428 U.S.52,96 S.Ct. 2831,49 L.Ed. 788; Paris Adult Theatre I v. Slaton, 413 U.S. 49, 93 S.Ct. 2628, 37 LEd.2d 446; Roe v. Wade, 410 U.S.113,93 S.Ct. 705,35 L.Ed.2d.147; Doe v. Bolton, 410 U.S. 179,93 S.Ct.739,35 L.Ed.2d. 201; and Eisenstadt v. Baird, 405 U.S.438,92 S.Ct. 1029,31 L.Ed.2d 349. See also People v. Privitera, 23 Cal.3d 697,153 Cal.Rptr.431, 591 P.2d 919. It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 355, is an exercise of Congressional authority to limit the patient's choice of

medication. This is clear under the decisions referred to above.

(2) The use of Laetrile is sought to be prevented because in the opinion of the Commissioner the proponents have not met the burden imposed by the agency procedures and by the statute to fulfill the premarketing requirements. These standards are impressive, but they can be, and are regularly met by the pharmaceutical houses.

It is apparent from the record that the proponents did not conduct the research and the laboratory testing required under the prevailing procedures, and it thus must be held that they did not meet their burden. The Court in Weinberger v. Hynson,Westcott & Dunning, 412 U.S. 609,93 S.Ct. 2469,37 L.Ed.2d 207, refers to the exclusion of drugs "for which there is no affirmative, reliable evidence of effectiveness." This is a reference to those FDA procedures and to the laboratory procedures.

(3) We agree with the district court that the 1938 grandfather provisions (21 U.S.C.,

Section 321(p)(1) are not applicable. The 1962 amendments added some new provisions. Public Law No. 87-781,Section 107(c)(4), 76 Stat. 788, reads in part as follows:

> "In the case of any drug, which on the day immediately preceding the enactment date (October 10,1962),(A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201(p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

It is apparent from the above quotation that the several requirements of the 1962 amendments are not in the alternative, but instead each must be met. It is also apparent that with the folk medicine aspect of the use of Laetrile the several requirements cannot be met. This is especially so as to the consistent labeling requirements since October of 1962. The record also demonstrates, not unexpectedly, that there has not been the consistency in the formula which the FDA requires under its current practice. In short,

the record does not support a conclusion that the several conditions in Pub.L.87-781 have been met to permit the application of the grandfather exceptions. In United States v. Allan Drug Corporation, 357 F.2d 713(10th Cir.), a condemnation case, we considered the 1962 amendments. We there said: "Since we are dealing with a Grandfather Clause exception, we must construe it strictly against one who invokes it."

Our mandate previously issued is recalled; the judgment of the district court is reversed, and the case remanded.

March Term - April 28, 1980

Before Honorable Oliver Seth, Chief Judge, Honorable William J. Holloway, Jr., Honorable James E. Barrett, Honorable William E. Doyle, Honorable Monroe G. McKay, Honorable James K. Logan, and Honorable Stephanie K. Seymour, Circuit Judges

GLEN L. RUTHERFORD, et al.,
Plaintiffs-Appellees
vs.
UNITED STATES OF AMERICA, et al.,
Defendants-Appellants
AMERICAN CANCER SOCIETY,
Amicus Curiae.

NO.77-2049

This matter comes on for consideration of the petition for rehearing and suggestion for rehearing en banc filed by the appellees in the captioned case.

Upon consideration whereof, the petition for rehearing is denied by the panel to whom the case was argued and submitted.

The petition for rehearing having been denied by the panel to whom the case was argued and submitted and no member of the panel nor judge in regular active service on the Court having requested that the Court be polled on rehearing en banc, Rule 35, Federal Rules of Appellate Procedure, the suggestion for rehearing en banc is denied.

Howard K. Phillips (signed)

HOWARD K. PHILLIPS, Clerk